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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/277,229	03/26/1999	MARTIN CITRON	A-581	3236

21069 7590 03/16/2005
AMGEN INC.
MAIL STOP 27-4-A
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THOUSAND OAKS, CA 91320-1799

EXAMINER

RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/16/2005

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/277,229

Applicant(s)

CITRON ET AL.

Examiner

Manjunath N. Rao, Ph.D.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-16 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Sequence Amendment

Art Unit: 1652

DETAILED ACTION

Claims 11-16 are currently pending and are present for examination. Claims 11-14 are now under consideration. Claims 15-16 remain withdrawn from consideration as being drawn to non-elected invention.

Applicants' amendments and arguments filed on 7-24-03, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Drawings

Drawings submitted in this application are accepted by the Examiner for examination purposes only.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Gurney(a) et al. (US 6,825,023 B1, 11-30-04, filed 4-12-00, priority date 9-24-1998). Claims 11-14 are drawn to an isolated biologically active β -secretase polypeptide selected from the group consisting of the polypeptides with SEQ ID NO:4, or fragments thereof, or a polypeptide with SEQ ID NO:4 but

Art Unit: 1652

having 1-50 conservative amino acid changes, wherein the polypeptide is encoded by a polynucleotide sequence with SEQ ID NO:1 or fragments thereof, or polynucleotides with conservative changes of 1-50 in the nucleotides of SEQ ID NO:1. Gurney et al. disclose and claim a polypeptide with SEQ ID NO:4 which is 100% identical to the polypeptide with SEQ ID NO:4 of the instant application (see enclosed sequence alignment). The above reference also discloses polynucleotide which encodes polypeptide SEQ ID NO:4, thereby anticipating the polypeptide and its fragments claimed in claims 11-14.

In response to the previous Office action in which a rejection was made using US Patents granted to Gurney et al. having the filing and priority dates as in the instant rejection, applicants have filed a Declaration under Rule 1.131, swearing behind the date of the previous references. However, in those cases claimed polypeptides were only disclosed in the references but not actually claimed. In the above rejection, the reference, a US patent actually claims the polypeptide claimed in the instant application and therefore a declaration filed under Rule 1.131 cannot be persuasive to overcome said rejection. However, applicants can request an interference pursuant to 37 CFR 41.202(a). Furthermore, applicant must comply with the requirements set forth in 37 CFR 41.202(a) 2-(a) (6).

Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura

Art Unit: 1652

Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Manjunath N. Rao, Ph.D.

Primary Examiner

Art Unit 1652

March 14, 2005

Db 421 HVHDEFRTAAVEGPFVTLDMEDCGYNIPOTDESTLMTIAYMAICALFMLPLCLMVCW 480
OY 481 RCLRCLRQOHHDFADDISLTK 501
Db 481 RCLRCLRQOHHDFADDISLTK 501

RESULT 8
US-09-548-368D-4
Sequence 4, Application US/09548368D

mw us 6,825,023. 11/30/04

APPLICANT: GURNEY ET AL.
TITLE OF INVENTION: ALZHEIMER'S DISEASE SECRETASE, APP SUBSTRATES THEREFOR AND USES
FILE REFERENCE: 28915/6280C
CURRENT FILING DATE: 2000-04-12
PRIOR APPLICATION NUMBER: US/09/548,368D
PRIOR FILING DATE: 1999-09-23
PRIOR APPLICATION NUMBER: US 60/155,493
PRIOR FILING DATE: 1999-09-23
PRIOR APPLICATION NUMBER: US 09/404,133
PRIOR FILING DATE: 1999-09-23
PRIOR APPLICATION NUMBER: PCT/US99/20881
PRIOR FILING DATE: 1999-09-23
PRIOR APPLICATION NUMBER: US 60/101,594
NUMBER OF SEQ ID NOS: 73
SOFTWARE: PatentIn version 3.1
SEQ ID NO 4
LENGTH: 501
TYPE: PRT
ORGANISM: Homo sapiens
US-09-548-368D-4

Query Match 100.0%; Score 2661; DB 19; Length 501;
Best Local Similarity 100.0%; Pred. No. 8.8e-269;
Matches 501; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

OY 1 MAQALPMLLMGAGVLPAGHGTGIRPLRSGGAPLGLRLPRETDEEPEEGRGSGF 60
Db 1 MAQALPMLLMGAGVLPAGHGTGIRPLRSGGAPLGLRLPRETDEEPEEGRGSGF 60
OY 61 VEMVDNLRGKSGGYYVEMTVGSPQTLNLIVDTGSSNFAVGAAPHFLHRYQROLST 120
Db 61 VEMVDNLRGKSGGYYVEMTVGSPQTLNLIVDTGSSNFAVGAAPHFLHRYQROLST 120
OY 121 YRDLRKGVYVYTGKKEGELGTDVSIPIGPNVTVRANIAITESDKFPLNGSMEGIL 180
Db 121 YRDLRKGVYVYTGKKEGELGTDVSIPIGPNVTVRANIAITESDKFPLNGSMEGIL 180
OY 181 GLAYAEIARPPDSLEPFDSLVKOTHPNLFSLQCGAGFPLNQEVLASVGSMTTGT 240
Db 181 GLAYAEIARPPDSLEPFDSLVKOTHPNLFSLQCGAGFPLNQEVLASVGSMTTGT 240
OY 241 DHSLYTGSLLWTPYIRREMYEVIIVREINGODLMDCKEYNDKSIYDSGTTNLRPKK 300
Db 241 DHSLYTGSLLWTPYIRREMYEVIIVREINGODLMDCKEYNDKSIYDSGTTNLRPKK 300
OY 301 VFEAAVSIKAASTEKEPFGFNLGEOLVVCQAGTTPWNIIPVISTLYLMEVYNQSFRT 360
Db 301 VFEAAVSIKAASTEKEPFGFNLGEOLVVCQAGTTPWNIIPVISTLYLMEVYNQSFRT 360
OY 361 ILPOQYLRPEVDVATSDDCYKFAISOSSTGTWGAIVMEGFVVPDRAKRIGFAVSAC 420
Db 361 ILPOQYLRPEVDVATSDDCYKFAISOSSTGTWGAIVMEGFVVPDRAKRIGFAVSAC 420
OY 421 HVHDEFRTAAVEGPFVTLDMEDCGYNIPOTDESTLMTIAYMAICALFMLPLCLMVCW 480
Db 421 HVHDEFRTAAVEGPFVTLDMEDCGYNIPOTDESTLMTIAYMAICALFMLPLCLMVCW 480
OY 481 RCLRCLRQOHHDFADDISLTK 501
Db 481 RCLRCLRQOHHDFADDISLTK 501